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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,059	12/29/2000	James R. Baker JR.	UM-04491	8985

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
09/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/751,059	BAKER ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/16/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *186,189-194,197 and 199-203* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *186,189-194,197 and 199-203* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/16/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time, IDS, amendment and remarks filed 6/16/08. Claims 186, 200 and 202 are amended. Claims 187 and 188 are canceled. Claims 186, 189-194, 197 and 199-203 are pending.

Response to Arguments

Previous rejections that are not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 202 and 203 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

3. The composition used in amended claim 202 to treat herpes simplex virus infection is new and as such introduces new composition concept into the specification as originally because the original specification does not possess the concept of a composition that consists of 1-6 in claim 202.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 186, 189-194, 197 and 199-201 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Libin (US 5,855,872) in view of Stroud et al. (US 6,231,837) for reasons of record and reiterated herein below.

Libin discloses method of treating diseased tissues that results from herpes simplex virus infection, by applying an oil in water emulsion that contains cetylpyridinium chloride, sterol alcohol, emulsifying agent and mineral oil (abstract; column 1, lines 42, 47-55; column 2, lines 26-64; column 3, line 25 to column 4 line 29) without specifically mentioning a human while disclosing topical application. Stroud teaches an oil in water emulsion (column 17, lines 51 and 52; column 18, lines 6 and 7; column 22, line 14) that is a self tanning composition (column 7,

lines 28,29; column 11, line 26; column 12, lines 29 and 30) that contains glycerol (column 7, lines 39 and 40; column 15, lines 41 and 42), ethanol (column 11, line 41), antimicrobial or antifungal agents (column 18, lines 43-46), preservatives or chelating agent such as EDTA helps maintain the ionic strength of the composition(column 19, lines 26, and 54-59), antiviral agent for treating herpes simplex or herpes zoster or chickenpox (column 21, lines 7-9), emollients such as castor oil or soybean oil (column 21, lines 29-32) and surfactant such as polysorbate 20 (column 24, lines 30, 50 and 51), which is TWEEN 20; the oil in water emulsion of Stroud is formulated as cream, lotion or ointment (column 17, lines 31, 32). Stroud teaches that the self-tanning formulations are approved for use with humans (column 2, lines 61 and 65). Regarding the %amounts of ethanol, surfactant and % volume oil, the ordinary skilled artisan has within his or her technical grasp to use amounts of oil, surfactant and ethanol desired in the composition that would be effective to treat herpes simplex virus. Both compositions have utility in the treatment of herpes simplex virus via topical route so that a combination of the compositions of Stroud and Libin will yield a composition that would be effective in treating herpes simplex virus. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the composition of Stroud and Libin with the motivation that topically applying the composition to affected areas of a person in need thereof, and specifically to humans in view of Stroud, would treat the affected areas of herpes simplex. Treating the virus results from inactivating the virus and thus leads to decontaminating the affected area.

The application to human the combined composition that contains alcohol, surfactant, oil and the cetylpyridinium chloride meets claims 186-188, 197 and 200. The presence of the ETDA meets claims 189, 190 and 201. The presence of oil or soybean oil meets claims 191 and

192. Polysorbate 20, which is TWEEN 20 meets claims 193 and 194. Ethanol present in the formulation meets claims 186, 200 and 202. The topical application of the formulation in the form of ointment or lotion or cream meets claims 186, 199 and 200.

7. Claims 186, 191, 193, 194 and 197-200 remain rejected under 35 U.S.C. 103(a) as unpatentable over Asculai et al. (US 4,020,183) in view of Keith et al. (US 4,350,707) for reasons of record.

Asculai discloses inactivating herpes simplex virus in humans by applying to the infected area an effective amount of oil-in-water emulsion that contains surfactants such as polysorbate 20, which is TWEEN 20 (column 1, line 61; Table 1), halogen containing compound such as cetylpyridinium chloride or benzalkonium chloride (column 1, lines 16 and 17), mineral oil of petrolatum (column 2, lines 48 and 49), alcohols (line 41), the formulation is in the form of cream or lotion (column 2, line 46). Asculai describes method of inactivating the herpes simplex virus in humans by applying the composition to the affected areas (claims 1-6) and while Asculai does not use the term decontamination, inactivation naturally leads to decontamination so that Asculai inherently decontaminates surfaces of the human. Asculai uses surfactant in amounts of between 0.5% and 20%. The composition of Asculai does not contain ethanol as now recited in claims 186 and 200. But Keith uses ethanol containing composition to topically treat herpes simplex virus. Therefore, given the teachings of Asculai and Keith, one of ordinary skill in the art at the time the invention was made would have reasonable expectation of success to inactivate or treat surfaces having the herpes simplex virus with the composition of Asculai to which has been ethanol. While the %ethanol used in Keith is higher than that recited,

the mere fact a range is claimed indicates that the amount of the ethanol can be optimized to produce the composition effective to treat the surface of virus.

Response to Arguments

8. Applicant's arguments filed 6/16/08 have been fully considered but they are not persuasive.

9. Applicant argues that a) the cited references, "individually or in combination do not teach or suggest method of topically treating a human having a *Herpes Simplex I virus* infection" by exposing the surface of a skin or mucosal cells and tissue of a human to nanoemulsion composition or dilution thereof (claim 186). The examiner disagrees. Libin in view of Stroud topically applies ointment (Libin at abstract, column 1, lines 21 and 49, column 5, line 13 and claim 4) comprising cetylpyridinium chloride, alcohol, mineral oil and emulsifying agent as described in the rejections; Stroud teaches that compositions such as that described for Libin is approved for use with humans . If the difference in applicant's view is the respective amounts of ethanol, surfactant and the halogen containing compound, halogen containing compound, it would be well within the technical grasp of the ordinary artisan to use amounts of ethanol, surfactant and halogen containing compound that would provide an emulsion that when topically applied to the human skin would treat diseased tissues resulting form herpes simplex virus infection. If the difference is that the prior art teaches emulsion and the claims recited nanoemulsion, it is noted that nanoemulsion is a type of emulsion (see definition of emulsion and nanoemulsion from Answers.com, http://www.answers.com/topic/emulsion). Topically applying nanoemulsion composition comprising disperse or oil phase, continuous or aqueous phase, 3-15% ethanol, 3-15% surfactant and 0.5-2% or 1-10% of halogen containing compound

is not inventive over the prior art that topically applies an emulsion comprising disperse or oil phase, continuous or aqueous phase, ethanol, surfactant and halogen containing compound in the absence of unexpected results. Applicant has not provided any factual showing.

10. b) the cited references, "individually or in combination do not teach or suggest method of topically treating a human having a *Herpes Simplex I virus* infection" by exposing the surface of a skin or mucosal cells and tissue of a human to nanoemulsion composition consisting essentially of 50-80% oil, distilled water, 3-15% ethanol, 3-15% surfactant and 0.5-2% or 1-10% cetylpyridinium chloride (claim 200). The examiner disagrees and the response is the same as above because the combined teachings of Libin, Stroud teaches oil in water emulsion (see abstract, Libin and column 17, lines 51 and 52). If the difference in applicant's view is the respective amounts of ethanol, surfactant and the halogen containing compound, halogen containing compound, it would be well within the technical grasp of the ordinary artisan to use amounts of ethanol, surfactant and halogen containing compound that would provide an emulsion that when topically applied to the human skin would treat diseased tissues resulting form herpes simplex virus infection. If the difference is that the prior art teaches emulsion and the claims recited nanoemulsion, it is noted that nanoemulsion is a type of emulsion (see definition of emulsion and nanoemulsion from Answers.com, http://www.answers.com/topic/emulsion). Topically applying nanoemulsion composition comprising disperse or oil phase, continuous or aqueous phase, 3-15% ethanol, 3-15% surfactant and 0.5-2% or 1-10% of halogen containing compound is not inventive over the prior art that topically applies an emulsion comprising disperse or oil phase, continuous or aqueous phase,

ethanol, surfactant and halogen containing compound in the absence of unexpected results. Applicant has not provided any factual showing.

11. Claims 202 and 203 are rejected under 35 U.S.C. 103(a) as being unpatentable over Libin (US 5,855,872) in view of Thomsen et al. (US 6,342,537, Thomsen 1) or Thomsen et al. (US 5,981,605, Thomsen II) and further in view of Mulder (US 5536502) and Asculai et al. (US 4,020,183).

12. Libin topically applies ointment (abstract, column 1, lines 21 and 49, column 5, line 13 and claim 4) comprising cetylpyridinium chloride, sterol alcohol, mineral oil and emulsifying agent as described in the rejections above for treating diseased tissues that results from herpes simplex virus infection (abstract; column 1, lines 42, 47-55; column 2, lines 26-64; column 3, line 25 to column 4 line 29) without specifically mentioning a human while disclosing topical application. Libin's composition also contains preservatives such as methyl paraben or propyl paraben (column 3, line 5). Libin uses sterol alcohol instead of ethanol. But ethanol is known to disinfect herpes simplex virus according to Thomsen 1 at column 23, lines 7-26) or Thomsen II at column 2, lines 40-42; column 4, lines 27-30; column 8, lines 17-23. However, it is known that EDTA and the parabens are preservatives (claim 12 of US 5536502) and one preservative can be used in place of the other without materially affecting the composition. Therefore, taking the teachings of the prior art, one having ordinary skill in the art at the tine the invention was made would have reasonable expectation of success that using ethanol in place of the sterol alcohol, and using EDTA in place of the parabens in the composition of Libin would effectively treat diseased tissues that results from herpes simplex virus infection. Furthermore, the composition of Libin can be topically applied to human since it is known in the art that

cetylpyridinium containing emulsion is known to inactivate herpes simplex virus in humans by applying to the infected area as evidenced by Asculai at column 1, line 61 and Table 1.

Response to Arguments

13. Applicant's arguments filed 6/16/08 have been fully considered but they are not persuasive.

14. The rejection immediately above is a new rejection in view of the amendment.

15. Applicant's argument c) that the cited references, "individually or in combination do not teach or suggest method of topically treating a human having a *Herpes Simplex I virus* infection" by exposing the surface of a skin or mucosal cells and tissue of a human to nanoemulsion composition consisting of 50-80% oil, distilled water, 3-15% ethanol, 3-15% surfactant and 0.5-2% or 1-10% cetylpyridinium chloride (claim 200) as it relates to the new rejection is not persuasive because ethanol is known in the art to inactivate Herpes simplex virus according the Thomsen I and II and as cited above so that ethanol can be used in place of the sterol alcohol; EDTA and the parabens are also known preservatives according to Mulder at claim 12 as described above so that EDTA can be used in place of the parabens. If the difference in applicant's view is the respective amounts of ethanol, surfactant and the halogen containing compound, halogen containing compound, it would be well within the technical grasp of the ordinary artisan to use amounts of ethanol, surfactant and halogen containing compound that would provide an emulsion that when topically applied to the human skin would treat diseased tissues resulting form herpes simplex virus infection. If the difference is that the prior art teaches emulsion and the claims recited nanoemulsion, it is noted that nanoemulsion is a type of emulsion (see definition of emulsion and nanoemulsion from Answers.com,

http://www.answers.com/topic/emulsion). Topically applying nanoemulsion composition comprising disperse or oil phase, continuous or aqueous phase, 3-15% ethanol, 3-15% surfactant and 0.5-2% or 1-10% of halogen containing compound is not inventive over the prior art that topically applies an emulsion comprising disperse or oil phase, continuous or aqueous phase, ethanol, surfactant and halogen containing compound.

No claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618